DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 1, 2014

DePuy Synthes Spine, *a Johnson & Johnson Company*
Ms. Jaclyn Porsolt
Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K142460
Trade/Device Name: Synapse System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNI, MNH
Dated: August 29, 2014
Received: September 2, 2014

Dear Ms. Porsolt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142460

Device Name
Synapse System

Indications for Use *(Describe)*
These Systems are intended for the following:

Hooks, Plate/Rods, Plates, Rods and Screws
When intended to provide stabilization as an adjunct to fusion of the cervical spine and occipitocervical junction (occiput-T3), the plate/rod, plates, rod, hook and screw (3.2 mm cortex) components of the Synthes CerviFix, Axon, OC Fusion and Synapse Systems are indicated for skeletally mature patients using allograft and/or autograft for the following:
• Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
• Spondylolisthesis
• Spinal stenosis
• Fracture/dislocation
• Atlantoaxial fracture with instability
• Occipitocervical dislocation
• Revision of previous cervical spine surgery
• Tumor

When used to treat these cervical and occipitocervical conditions, screws are limited to occipital fixation only.

Hooks and Rods
The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Rods, Clamps, Screws, Nuts, Variable Axis Screws, Locking Screws and Transverse Bars
The rods, clamps, screws, nuts, variable axis screws, locking screws and transverse bars are intended to promote fusion following reduction of fracture/dislocation or trauma in the upper thoracic spine (T1-T3).

The use of these screws (3.5 mm, 4.0 mm and 4.5 mm cancellous and 3.5 mm and 4.2 mm cortex) is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in or treat conditions involving the cervical spine.

The Synthes CerviFix, Axon, and Synapse Systems can also be linked to the Synthes Universal Spinal System using the 3.5 mm/6.0 mm and 4.0 mm/6.0 mm parallel connectors from that system and via the CerviFix tapered rods using lamina hooks, transverse process hooks, pedicle hooks, 4.2 mm screws, and the 5.0 mm/6.0 mm parallel connector.

The Synthes Synapse System can be linked to the DePuy EXPEDIUM 5.5 Titanium Spine System using the 3.5 mm/5.5 mm and 4.0 mm/5.5 mm titanium tapered rods.

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic (T4-T12) or lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

A. Submitter Information

DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767

Contact Person:	Jaclyn Porsolt
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Telephone number:	(508) 828-3269
Fax number:	(508) 828-3797
Email:	jporsol1@its.jnj.com

B. Date Prepared September 30, 2014

C. Device Name

Trade/Proprietary Name:	Synapse System
Common/Usual Name:	Spinal Interlaminal Fixation Orthosis
Classification and Regulation:	Class II per 21 CFR 888.3050
Classification Product and Panel Code:	KWP; Orthopedic
Subsequent Regulation:	21 CFR 888.3070
Subsequent Classification Product and Panel Code:	MNI; Orthopedic MNH; Orthopedic

D. Predicate Device Name

Trade names: Primary Predicate: Synthes Synapse System (most recently cleared K091689)
Additional Predicate: DePuy EXPEDIUM Spine System (most recently cleared K111136)
Additional Predicate: Synthes Matrix Spine System (K100634)

E. Device Description

The tapered rods are intended to create a single construct by linking system components that receive different rod diameters. These rods are manufactured from titanium-aluminum-niobium (Ti-6Al-7Nb (TAN)). These rods taper from a diameter of 3.5 mm or 4.0 mm to a diameter of 5.5 mm and are both 500 mm in length.

The Synthes Synapse System is a hook, rod and pedicle screw spinal system intended to provide posterior stabilization of the upper spine (C1-T3) as an adjunct to fusion in skeletally mature patients. This system consists of multiple components manufactured from either titanium aluminum niobium (Ti-6Al-7Nb (TAN)) or commercially pure grade 4 Titanium and include rods (straight, tapered and curved), plate/rods, hooks, clamps, screws, nuts, variable axis screws, locking screws, transconnector clamps, transverse bars, parallel connectors and variable axis/top loading transconnectors. These system components are implanted using Class I general surgical instruments. A complete occipital-cervical-thoracic construct can be created by using components from the previously cleared Synthes CerviFix System, Synthes Axon System, and Synthes OC Fusion System. When combined with the Synthes Universal Spinal System (including Matrix) using parallel connectors or tapered rods, constructs can extend from the occiput to the lower spine.

F. Intended Use (proposed changes highlighted in blue font)

Synthes Synapse System
These Systems are intended for the following:

Hooks, Plate/Rods, Plates, Rods and Screws
When intended to provide stabilization as an adjunct to fusion of the cervical spine and occipitocervical junction (occiput-T3), the plate/rod, plates, rod, hook and screw (3.2 mm cortex) components of the Synthes CerviFix, Axon, OC Fusion and Synapse Systems are indicated for skeletally mature patients using allograft and/or autograft for the following:

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- Tumor

When used to treat these cervical and occipitocervical conditions, screws are limited to occipital fixation only.

Hooks and Rods
The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Rods, Clamps, Screws, Nuts, Variable Axis Screws, Locking Screws and Transverse Bars
The rods, clamps, screws, nuts, variable axis screws, locking screws and transverse bars are intended to promote fusion following reduction of fracture/dislocation or trauma in the upper thoracic spine (T1-T3).

The use of these screws (3.5 mm, 4.0 mm and 4.5 mm cancellous and 3.5 mm and 4.2 mm cortex) is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in or treat conditions involving the cervical spine.

The Synthes CerviFix, Axon, and Synapse Systems can also be linked to the Synthes Universal Spinal System using the 3.5 mm/6.0 mm and 4.0 mm/6.0 mm parallel connectors from that system and via the CerviFix tapered rods using lamina hooks, transverse process hooks, pedicle hooks, 4.2 mm screws, and the 5.0 mm/6.0 mm parallel connector.

The Synthes Synapse System can be linked to the DePuy EXPEDIUM 5.5 Titanium Spine System using the 3.5 mm/5.5 mm and 4.0 mm/5.5 mm titanium tapered rods.

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic (T4-T12), or lumbar spine.

G. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The technological characteristics of the tapered rods and Synapse System that are the subjects of this submission remain unchanged from their predicate versions in their design, material, and performance. The intended use of the subject devices also remains unchanged from their predicate versions.

H. Materials

The tapered rods, which are the subject of this submission, previously cleared with the Matrix System, are available in titanium alloy conforming to ASTM F-1295 specifications.

The previously cleared Synapse System components are available in titanium alloy conforming to ASTM F-1295 specifications.

I. Performance Data

Since the subject devices have been extensively tested in their predicate submissions and their designs and technological characteristics remain unchanged, an engineering rationale is provided in lieu of performance testing for the proposed modification.

J. Conclusion

Substantial Equivalence Justification demonstrates that the devices are as safe, as effective, and perform as well as the predicate devices because the intended use and technological characteristics remain unchanged. The engineering rationale further demonstrates that the subject tapered rods can be added to the Synapse System to expand the system’s compatibility for use with the EXPEDIUM Spine System.